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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/818,086	03/26/2001	Dale Baskin	7414.0043	2844

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EXAMINER	
TUNG, JOYCE	
ART UNIT	PAPER NUMBER
1637	

DATE MAILED: 09/24/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action

Application No.	Applicant(s)
09/818,086	Baskin et al.
Examiner	**Art Unit**
Joyce Tung	1637

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED *Aug 11, 2003* FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid the abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

THE PERIOD FOR REPLY [check only a) or b)]

a) ☐ The period for reply expires _____ months from the mailing date of the final rejection.

b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☒ A Notice of Appeal was filed on *Aug 11, 2003*. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.

2. ☐ The proposed amendment(s) will not be entered because:

(a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);

(b) ☐ they raise the issue of new matter (see NOTE below);

(c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or

(d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____

3. ☐ Applicant's reply has overcome the following rejection(s):

4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because:
Please see the attached

6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.

7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☐ will not be entered or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: _____

Claim(s) objected to: _____

Claim(s) rejected: *1-50 and 68*

Claim(s) withdrawn from consideration: _____

8. ☐ The proposed drawing correction filed on _____ is a) ☐ approved or b) ☐ disapproved by the Examiner.

9. ☒ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). *10*.

10. ☐ Other:

Claims 1-68 are pending. Claims 1-50 and 68 are rejected and claims 51-67 are withdrawn.

1. Claims 10 and 35 remain rejected under 35 U.S.C. §112, second paragraph in section 2(a) of the final office action mailed 2/11/2003 because it is still unclear whether or not the nucleic acid from the virus or prokaryote as listed in the claims is chemically modified. Clarification is required.

The response argues that the nucleic acid derived from a virus or prokaryote in claims 10 and 35 may or may not be chemically modified. The response further states that "During patent examination, the pending claims must be given the broadest reasonable interpretation consistent with the specification" (See MPEP, § 2173.05(a)). However, based upon the phase "derived from" in the art, it describes a chemical compound which has chemical modification. It is unclear whether or not the nucleic acid from the virus or prokaryote as listed in the claims is chemically modified. By in large, the sample from virus or other living things are not chemically modified. Unless, there is a step to chemically modify the sample. Thus, clarification is required and the rejection is maintained.

2. Claims 26-50 remain rejected under 35 U.S.C. §112, second paragraph in section 2(b) of the final office action mailed 2/11/2003 because it is still unclear how the sequence of the at least one amplification product of the first reaction composition is determined since the first reaction composition does not has a fluorescence indicator. The clarification is required.

The response argues that the amplification product of the first reaction composition may be determined by as a non-limiting example that does not use a fluorescent indicator. It is true However, it is unclear whether or not the amplification products from the second composition is from the amplification products produced by the first composition. Thus it is unclear how to determine whether the at least one amplification product is present in both the first reaction composition and the second reaction composition from the intensity of signal from the fluorescent indicator in the second reaction composition. Another words, there is no a relation between the first composition and second composition. Thus, the rejection is maintained.

3. The rejection of claim 49 under 35 U.S.C. §112, second paragraph in section 2(c) is withdrawn.

4. Claims 1-25 and 68 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Pritham et al. (J of Clinical Ligand Assay, 1998, Vol.(4), pg. 404-412) in view of Johnston-Dow et al. (6,103,465).

The response argue that there is no indication that the references suggest a motivation to combine the references. However, in the last step of claim 1 it states "determining the sequence of the at least one amplification product if the at least one amplification product is present" without any specified steps for sequencing. Thus as long as any method which is used for sequencing, it would have been used for "determining the sequence of the at least one amplification product if the at least one amplification product is present". The method of Johnson-Dow et al. is applied to the locus-specific nucleic acid amplification followed by

sequence-specific detection of the amplified product for the DNA typing of HLA class I gene via DNA sequencing in that by sequencing the exons in both directions, the effect of sequencing errors on the assignment of HLA type is minimized and the method greatly reduces the number of reagents and the complexity of the sequencing protocols required (See column 9, lines 29-37). Because of the benefit of using the DNA sequencing of Johnson-Dow et al., one of ordinary skill in the art would have been motivated to apply the sequencing method of Johnson-Dow et al. to determine the sequence of the at least one amplification product if the at least one amplification product is present. Thus, the rejection is maintained.

5. Claims 26-50 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Pritham et al. (J of Clinical Ligand Assay, 1998, Vol.(4), pg. 404-412) in view of Johnston-Dow et al. (6,103,465) as applied to claims 1-25 and 68 above, and further in view of Wittwer et al. (6,174,670).

The response does not have specific argument regarding the rejection, thus the rejection is maintained.

6. Any inquiries concerning this communication or earlier communications from the examiner should be directed to Joyce Tung whose telephone number is (703) 305-7112. The examiner can normally be reached on Monday-Friday from 8:00 AM-4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached at (703) 308-1119 on Monday-Friday from 10:00 AM-6:00 PM.

Any inquiries of a general nature or relating to the status of this application should be directed to the Chemical/Matrix receptionist whose telephone number is (703) 308-0196.

7. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Art Unit 1637 via the PTO Fax Center located in Crystal Mall 1 using (703) 305-3014 or 308-4242. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989).

Joyce Tung

September 10, 2003

JEFFREY SIEW
PRIMARY EXAMINER
9/4/03